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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,055	03/11/2002	Vincent Mooser	P07484US00/BAS	7170

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EXAMINER	
KOLKER, DANIEL E	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 02/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/030,055	MOOSER ET AL.	
	Examiner	Art Unit	
	Daniel Kolker	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 March 2002 and 27 May 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-20* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Possible Claim Objections

The claims may be objected to because of the following informalities:

1) Claim 3 recites "a method according to *clam* 1" (emphasis added)

2) Claim 4 recites "ma patient"

3) Claim 14 recites "disulfide *brides*" (emphasis added)

Appropriate correction is suggested.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The first stated special technical feature is a method of predicting increased risk of a patient having Alzheimer's disease, comprising assaying a DNA-containing biological sample for the allele of the APOE gene and assaying the plasma level of protein Lp(a).

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1 (in part) and 2 (in part), drawn to methods of predicting an increased risk of having Alzheimer's disease wherein the plasmatic level of [Lp(a)]/Apo(a) is determined by an immunoenzymatic assay.

Group II, claim(s) 1 (in part), 2 (in part) and 3, drawn to methods of predicting an increased risk of having Alzheimer's disease wherein the plasmatic level of Lp(a)/Apo(a) is assayed by means of a sandwich assay.

Group III, claim(s) 1 (in part) and 4, drawn to methods of predicting an increased risk of having Alzheimer's disease wherein DNA is amplified.

Group IV, claim(s) 5 (in part), 6, and 8 (in part), drawn to kits, to the extent that the claims read on reagents to assay for the presence of the APOE ε4 allele in a DNA sample.

Group V, claim(s) 5 (in part), 7, and 8 (in part), drawn to kits, to the extent that the claims read on primers which are capable of amplifying at least a portion of the APOE gene.

Group VI, claim(s) 5 (in part) and 9, drawn to kits, to the extent that the claims read on antibodies recognizing Lp(a)Apo(a).

Group VII, claim(s) 10 (in part) and 11 (in part), drawn to methods of treating diseases, wherein the compound is danazol.

Group VIII, claim(s) 10 (in part) and 11 (in part), drawn to methods of treating diseases, wherein the compound is retinoic acid.

Group IX, claim(s) 10 (in part) and 12, drawn to methods of treating diseases, wherein the compound is an oligonucleotide ribozyme.

Group X, claim(s) 10 (in part), 13 (in part), and 14, drawn to methods of treating diseases, wherein the compound is an antioxidant.

Group XI, claim(s) 10 (in part), 13 (in part), and 15, drawn to methods of treating diseases, wherein the compound is catanospermine.

Group XII, claim(s) 10 (in part), 13 (in part), and 16, drawn to methods of treating diseases, wherein the compound is an antibiotic of the deoxystreptamine family.

Group XIII, claim(s) 10 (in part), 13 (in part), and 17 (in part), drawn to methods of treating diseases, wherein the compound is an analog of lysine.

Group XIV, claim(s) 10 (in part), 13 (in part), and 17 (in part), drawn to methods of treating diseases, wherein the compound is an analog of argenine.

Group XV, claim(s) 10 (in part), 13 (in part), and 17 (in part), drawn to methods of treating diseases, wherein the compound is an analog of phenylalanine.

Group XVI, claim(s) 10 (in part), 13 (in part), and 17 (in part), drawn to methods of treating diseases, wherein the compound is an antibody.

Group XVII, claim(s) 10 (in part), 13 (in part), and 18 - 19, drawn to methods of treating diseases, wherein the compound blocks the binding site of Apo(a).

Group XVIII, claim(s) 10 (in part), 13 (in part), 17 (in part) and 20 (in part), drawn to methods of treating diseases, wherein the compound is alpha-2 macroglobulin.

Group XIX, claim(s) 10 (in part), 13 (in part), 17 (in part) and 20 (in part), drawn to methods of treating diseases, wherein the compound is a surface proteoglycan.

The inventions listed as Groups I - XIX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Group I is drawn to diagnostic methods wherein an immunoassay is used to assay plasmatic levels of [Lp(a)]/Apo(a). Groups II and III are drawn to other diagnostic methods which are not linked to the methods of Group I. A sandwich assay is not required, as the method of Group I could be

performed with a single-antibody assay. A DNA-amplifying method is not required for Group I, as it could be performed with a hybridization assay. Claims IV – XIX are drawn to diagnostic kits and therapeutic methods, neither of which is required to practice the method of Group I. Therefore the inventions are not linked by a special technical feature as defined by PCT Rule 13.2.

Requirement for Election of Species in Groups I – III and VI

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

a) Methods of predicting risk of Alzheimer's disease comprising assaying Lp(a)

b) Methods of predicting risk of Alzheimer's disease comprising assaying Apo(a)

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Claims 1 and 5 recite both Lp(a) and Apo(a).

The following claim(s) are generic: 1 - 9.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the species are independent proteins with unique structure and chemical characteristics. Methods of detecting Lp(a) are distinct from methods of detecting Apo(a), and separate antibodies can be used. Therefore the methods are linked by a common special technical feature.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the

product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel Kolker whose telephone number is (571) 272-3181. The examiner can normally be reached on Mon - Fri 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SHARON L. TURNER, PH.D.
PATENT EXAMINER
2-10-05

Daniel E. Kolker, Ph.D.
February 7, 2005